

Meeting Date October 26, 2004

12-1 PM EDT

Attendees:

Working Group Coordinators: Scott Finley (Booz Allen Hamilton) Harshawardhan Bal (Booz Allen Hamilton)

Participants:

i aiticipants.		
Andrea Hwang	Chao Family Comprehensive Cancer Center	ychwang@uci.edu
Anne Tompkins	СТЕР	tompkinsa@ctep.nci.nih.go v
Ben Greenbowe	Holden Comprehensive Cancer Center – U. Iowa	benjamin- greenbowe@uiowa.edu
Barry Brown	University of Minnesota Cancer Center	brown181@umn.edu
Bob Morrell	Wake Forest Comprehensive Cancer Center	bmorrell@wfubmc.edu
Brenda Crocker	University of Pittsburgh Cancer Institute	crockerbl@upmc.edu
Christos Andonyadis	NCICB	andonyac@mail.nih.gov
Christine Richardson	Booz Allen Hamilton	richardson_christine@bah. com
Dave Rose	Department of Veterans Affairs Office of Research and Development's Cooperative Studies Program	<u>David.Rose@med.va.gov</u>
Dave Aronow	Ardais	DrData@ardais.com
Deborah Collyar	Patient Advocates in Research (PAIR)	collyar@att.net
Diane Paul	CARRA	funnylady93@earthlink.net
Donald Connelly	Minnesota	don@umn.edu
Donna Marlatt	Dartmouth	donna.marlatt@dartmouth. edu
Douglas Fridsma	University of Pittsburgh Cancer Institute	fridsma@cbmi.pitt.edu
Jieping Li	Lombardi Cancer Research Center	lj38@georgetown.edu
Jill Kuennen	Holden Comprehensive Cancer Center – U. Iowa	jill-kuennen@uiowa.edu
John Quigley	Abramson Cancer Center	johnq@mail.med.upenn.ed u
John Speakman	Memorial Sloan-Kettering Cancer Center	speakman@biost.mskcc.or g
Joyce Niland	City of Hope National Medical Center & Beckman Research Institute	
Karen Kimura	UCSF Cancer Center & Cancer Research Institute	kkimura@cc.ucsf.edu



Karen Martier	CTSU	KarenMartier@westat.com
Kim Diercksen	NCICB	diercksk@mail.nih.gov
Linda Schmandt	UPMC	schmandtlm@upmc.edu
Lara Fournier	OHSU Cancer Institute	fourniel@ohsu.edu
Marjorie van der Pas	IMPAC Medical Systems, Inc.	mvanderpas@impac.com
Marsha Ketcham	University of Nebraska Medical Center/Eppley Cancer Center	mketcham@unmc.edu
Mary Jo Deering	NCICB	deeringm@mail.nih.gov
Michael Davis	University of Pittsburgh Cancer Institute	davismk@upmc.edu
Olag Shats	University of Nebraska Medical Center/Eppley Cancer Center	oshats@unmc.edu
Pavla Frazier	frazierp@mail.nih.gov	NCICB
Prakash Nadkarni	Yale Cancer Center	prakash.nadkarni@yale.ed u
Robert Lanese	Case Western Reserve - Ireland Cancer Center	robert.m.lanese@case.edu
Simon Sherman	University of Nebraska Medical Center/Eppley Cancer Center	ssherm@unmc.edu
Sorena Nadaf	Vanderbilt-Ingram Cancer Center	s.nadaf@vanderbilt.edu
Sudhir Raju	CTIS, Inc.	sraju@ctisinc.com
Susan Pannoni	City of Hope	spannoni@COH.org
Sue Dubman	NCICB	dubmans@mail.nih.gov
Teri Melese.	UCSF Cancer Center & Cancer Research Institute	tmelese@cc.ucsf.edu
Terry Braun	Holden Comprehensive Cancer Center – U. Iowa	tabraun@eng.uiowa.edu

Agenda

- 1. Funded Workspace participation
- 2. Update on SOWs
- 3. Reminder: CTMS face-to-face meeting Tuesday, 11/16 & Wednesday, 11/17 Location: City of Hope, Duarte, CA
- 4. Report from SIGS
 - caBIG compatibility: Teri Melese
 - Structured Protocol Representation: Doug Fridsma
 - Adverse Event Reporting: Joyce Niland



- CTMS/CDUS Reporting: Rhoda Arzoomanian
- Financial-Billing: Jill Kuennen
- Laboratory Interfaces: John Speakman
- 5. Next Meeting 11/09/04

1. General discussion points raised by participants:

1. Funded Workspace Participation:

- First funds for Workspace participation have been released (Bob Morrell, Wake Forest Comprehensive Cancer Center) indicating that the process of task order submission, approval of deliverables and invoicing has been successfully completed.
- Monthly reports: Most Centers have submitted. These are an opportunity for Cancer Centers to highlight their contributions to the Grid, as well as benefits realized from the Grid. Monthly reports are also the triggers (when approved) to permit invoicing for Participation.
- Every Center should be assisting with the operation of the Workspace in some way. Cancer Centers should actively contribute to the grid by participating in activities such as meeting minutes, acting as liaisons, white papers, etc.
- Training sessions on caMP and CVS were held and were attended by a large number of Cancer Centers
- 2. Cross-Workspace reports were added to assist sharing of knowledge and experiences from across caBIG Workspaces and to help follow the progress of the grid. John Speakman and Christine Richardson presented the Tissue Banking and Pathology Tools and the Vocabularies and Common Data Cross-Workspace reports.

John Speakman: Three products in development in the Tissue Bank and Pathology Tools Workspace:

- caTISSUE: a specimen tracking system
- caTISSUE Lite: a local system within centers for tissue processing and storage
- caTIES: for text mining of path reports to identify and remove PHI

There were questions regarding the scope of caTISSUE (whether it will include microarray data, whether it interacts with existing clinical trials management system) and caTIES (accuracy of deleting PHI information, especially with respect to names that match common English language terms). The Tissue Bank and Pathology Tools Workspace will be holding their first face-to-face meeting in the last week of November. The Workspace will be organized into SIGs including a compatibility SIG (which will focus on the development of compatibility guidelines) and an IRB SIG.

Christine Richardson: gave an update on the activities of the vocabularies and CDEs mentoring team. The mentoring teams consist of people who are from participating Cancer Centers as well as experts from NCI and NCICB who are well versed in technologies such as caCORE, EVS and caDSR. These teams will assist the Workspaces and the Cancer Centers to create



CDEs and ontologies, facilitate liaison activities between VCDE and the Cancer Centers and the caBIG community as a whole. Christine Richardson mentioned that Tom Johnson, Sharon Elcombe (Mayo Clinic) and Hemant Shah (City of Hope) would be part of the mentoring team and would help in CDE development issues. Training in CDEs development will be provided by Denise Warzel (NCICB) and described on the caDSR website.

3. Update on SOWs

- Structured Protocol Development Task Order issued
- caBIG Compatibility (UPMC) Task Order issued
- First AE Reporting Developer SOW Cost Proposal stage
- First CDE SOW in discussion
- Drafts of two more caBIG Compatibility SOWs in discussion
- Drafts of first four adopter SOWs in discussion
- In planning: Structured Protocol Representation Adopter SOWs work with UPMC
- **4. City of Hope Face-to-face meeting reminder:** The CTMS face-to-face meeting will be held Tuesday, November 16, and Wednesday, November 17, at City of Hope, in Duarte, CA. participants were reminded to send in their registration information to Jennifer Neat (City of Hope, jneat@COH.org). Joyce Niland added that COH is looking into the possibility of having a teleconference link up for remote participation.

5. Report from SIGs

- caBIG compatibility (Teri Melese, John Speakman): Develop the agenda
 for the face-to-face meeting in consultation with Arumani Manisundaram
 at the November 5 CTMS Compatibility Grading SIG teleconference,
 especially with respect to revision of the compatibility guidelines.
 Requested representation from the architecture group on the CTMS
 teleconference calls. Submitted UCSF caBIG compatibility SOW; Karen
 Kimura to follow up with Sue Dubman on specific aspects of the SOW.
- Adverse Effects Reporting (Joyce Niland): Updated responses to the Adverse Events Reporting CTMS/CDUS Reporting survey. Awaiting response on the Adverse Events reporting SOW. Represented caBIG and CTMS at the AACI conference and met with Velos and PercipEnz. Working on 3 and 5 year plans for the Workspace (activities, use cases, modeling) for the Strategic Planning Committee meeting.
- Structured Protocol Representation (Doug Fridsma): In the process of identifying the key components of a clinical trial registry which will serve as the foundation for the structured protocol representation work. Also in the process if identifying stakeholders, including commercial software companies and discovered that they hold patents on them and this may affect the caBIG work. Will engage in a modeling session with CDISC at the face-to-face meeting. Developed use cases for the architecture Workspace. Distributed survey by Linda Schmandt and Valerie Monaco over structured protocol representation project. Karen



Martier to follow upon the participation of cooperative groups and act as a liaison for the structured protocol representation with Doug Fridsma.

- CTMS/CDUS Reporting SIG (Sorena Nadaf for Rhoda Arzoomanian):
 Develop white paper for harmonization of data fields in CTMS and
 CDUS, preparation of reports from data submissions, acknowledgement
 of data submission preferences, definition of security and submission
 standards. Held conferences with Warren Kibbe on testing data
 transmission between Vanderbilt University and Northwestern University
 based on web services portal.
- Financial-Billing SIG (Jill Kuennen): Develop a description of the financial billing module with Michael Davis (UPMC), which has created a component model of how the financial billing module will interact with the structured protocol representation module of a Clinical Trials Management Systems. Ben Greenbowe is drafting use cases from the manual financial billing process at U lowa.
- Lab interfaces (John Speakman): Presented update on the CDISC lab model after consulting with Phil Pochon and Freddie Paino. Planning to send a Lab Interfaces survey.

Action Items:

Distribute meeting minutes